

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Anti-Infective Drugs Advisory Committee Meeting
Hilton Washington DC/Gaithersburg
December 10, 2009

AGENDA
OPEN SESSION

*The committee will discuss New Drug Application (NDA) 050-814, inhaled aztreonam, manufactured by Gilead Sciences, Inc., for the proposed indication of improvement of respiratory symptoms and pulmonary function in cystic fibrosis patients with **Pseudomonas aeruginosa**, a bacterial infection.*

8:00 – 8:15 a.m.	Call to Order & Introduction of Committee Committee Chair
	Conflict of Interest Statement Minh Doan, Pharm.D., Designated Federal Officer
8:15 – 8:30 a.m.	Regulatory Background
8:30 – 9:45 a.m.	<u>Applicant's Presentations</u> Gilead Sciences, Inc.
9:45 – 10:15 a.m.	Questions/Clarifications
10:15 – 10:30 a.m.	Break
10:30 – 11:30 a.m.	<u>FDA Presentations</u>
11:30 a.m. – 12:00 p.m.	Questions/Clarifications
12:00 – 1:00 p.m.	Lunch
1:00 - 2:00 p.m.	Open Public Hearing
2:00 – 4:00 p.m.	Charge and Questions to the Committee
4:00 p.m.	Adjournment